DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-655/S-036
NDA 19-910/S-024
NDA 20-518/S-008

GlaxoSmithKline
Attention: Martha Anne A. Moore, RPh
Product Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug applications dated August 4, 2000 and received August 5, 2000 submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for RETROVIR® (zidovudine) Capsules, RETROVIR® (zidovudine) Syrup, and RETROVIR® (zidovudine) Tablets.

These supplemental new drug applications were submitted in response to the Division's comments about needed revisions to the RETROVIR labeling and provide for changes in the following sections of the final printed labeling:

1. Addition of Geriatric Use Labeling in the PRECAUTIONS section
2. Copyright and Patent Information

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications, with the minor changes listed above, are approved effective on the date of this letter.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavyweight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-655/S-036, 19-910/S-024, 19-518/S-008." Approval of these submissions by FDA is not required before the labeling is used. However, marketing the

product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Marsha S. Holloman, BS Pharm, JD, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra B. Birnkrant, MD
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Printed Labeling Submitted August 4, 2000 by Sponsor

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Debra Birnkrant
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NDA 19-910 SLR 024